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K024057
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510(k) Summary
Curad® Scar Therapy

I. General Information on the Submitter:

Name:	Beiersdorf Inc.
Address:	5801 Mariemont Avenue Cincinnati, Ohio 45227
Telephone:	513.272.5060
Contact Person:	Mr. Richard Taylor
Date Summary Prepared:	December 9, 2002

II. General Information on Device:

Proprietary name:	Curad® Scar Therapy
Classification Name:	Elastomer, silicone, for scar management
Common Name:	Scar management sheet, bandage, pad, patch, or material
Class:	Not classified

III. Predicate Devices:

Curad® Scar Therapy is substantially equivalent to the Cutinova®thin Wound Dressing (K94-4581) and the Mepiform Adherent Silicone Dressing for Scar Care (K97-4354).

IV. Description of the Device:

Curad® Scar Therapy is a semi-occlusive, flexible pad for the management of hypertrophic scars resulting from burns, surgery, or injuries, after complete healing. The device is also intended for management of keloid scars. It may be used as a prophylactic therapy on closed wounds which may prevent hypertrophic and keloid scarring. It is intended for over-the-counter use.

Curad® Scar Therapy consists of an adhesive aliphatic polyurethane matrix. Embedded in this matrix are absorbent sodium polyacrylate particles. The product has a waterproof polyurethane film that is permeable to oxygen and water vapor.

The Curad® Scar Therapy pads are individually sealed in envelopes and packaged in cartons of 21 pads. The size of the pads is 7x4 cm. The pad is intended to

be exchanged daily for a new pad, and may remain in place 24 hours a day. Treatment should consist of at least 12 hours a day for at least eight weeks.

V. Intended Use:

Curad® Scar Therapy is intended for the management of hypertrophic and keloid scars. It may be used as a prophylactic therapy on closed wounds which may prevent hypertrophic and keloid scarring.

VI. Summary of Substantial Equivalence

In terms of its composition or technological characteristics, Curad®Scar Therapy is identical, and therefore substantially equivalent, to Beiersdorf's Cutinova®thin Wound Dressing, cleared for marketing under 510(k) number K94-4581. The safety of this polyurethane pad for application to both compromised and intact skin has been demonstrated with biocompatibility studies and long-term use. Thus, Curad®Scar Therapy, which is applied only to intact skin, does not raise new issues of safety.

Curad®Scar Therapy has the same intended use and principle of operation as, and is therefore also substantially equivalent to, the Mepiform product. Clinical studies have demonstrated that Curad®Scar Therapy is as effective as the Mepiform in the management and reduction of hypertrophic and keloid scars. Therefore, Curad®Scar Therapy does not raise new issues of efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2003

Beiersdorf, Inc.
c/o Ms. Frances K. Wu
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, D.C. 20005-5929

Re: K024057
Trade/Device Name: Curad® Scar Therapy
Regulatory Class: Unclassified
Product Code: MDA
Dated: April 2, 2003
Received: April 3, 2003

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024057

Device Name: Curad® Scar Therapy

Indications For Use:

Intended for the management of hypertrophic and keloid scars. May be used as prophylactic therapy on closed wounds which may prevent hypertrophic and keloid scarring.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K024057